IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

STATE OF OKLAHOMA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 4:05-CV-00329 GKF (PJC)
	)	
TYSON FOODS, INC., et al.,	)	
	)	
Defendants.	)	

STATE OF OKLAHOMA'S RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF VALERIE J. HARWOOD PURSUANT TO *DAUBERT v. MERRELL PHARMACEUTICALS, INC.*

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The State of Oklahoma ("the State") hereby submits this response in opposition to Defendants' motion to exclude the testimony of Valerie J. Harwood ("Dr. Harwood"). The Court should deny Defendants' motion for the following reasons.

I. Introduction

Defendants seek to exclude Dr. Harwood's testimony on the poultry specific biomarker (the "Biomarker") as well as her testimony regarding the risks to human health that are associated with land application of poultry waste. As shown below, the Biomarker was based on well-accepted scientific theory and methodology that is part of the science of microbial source tracking ("MST"). Furthermore, the underlying scientific theory and methodology was reliably applied in its development. The Biomarker is and has been subject to testing, the Biomarker has been peer reviewed, and the Biomarker has a known or potential rate of error. With respect to Dr. Harwood's opinion concerning the risk to human health of Defendants' practice of land applying in the IRW, the discussion below demonstrates that her opinion is not based solely on the Biomarker, but was formed prior to the Biomarker's identification and is validated based on well known, reliable methods of environmental evaluation as set out in her Expert Report ("Report").

These methods of evaluation include consideration of the known pathogens in poultry waste, the volume of poultry waste generated in the IRW, the method of poultry waste disposal in the IRW, the relative amounts of bacteria contributed by poultry as opposed to other sources of IRW bacteria, and the significant concentrations of bacteria running off of fields applied with poultry waste following rainfall. Furthermore, the water testing methods were reliable.

II. Discussion

A. Legal Standard.

The basis for admitting expert opinions such as that provided by Dr. Harwood is Rule 702 of the Federal Rules of Evidence:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

As an initial matter, the court must determine if the expert is qualified by "knowledge, skill, experience, training, or education" to render an opinion. *Id.* In this case Defendants do not contest Dr. Harwood's expertise in the subject areas in which she will testify. Indeed, a review of Dr. Harwood's experience and qualifications indicates the she is one of the leading scientific experts in the field of MST and regularly asked by state and federal environmental agencies to perform MST investigations, contribute to MST guidance documents, teach at government agency seminars, and publish peer reviewed articles on this topic. *See,* Exhibit A (Report at para. 1 -3), Exhibit B (Harwood CV) and Exhibit C (Harwood Decl. at para.2).

Next, a court must ensure that the scientific testimony being offered is "not only relevant, but reliable." *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). This is the issue raised by Defendants' motion when they challenge the opinions offered by Dr. Harwood on the Biomarker and the risk associated with their land application of poultry waste. "To be reliable under *Daubert*, an expert's scientific testimony must be based on scientific knowledge . . . ." *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1222 (10th Cir. 2003). The Supreme Court has explained that the term "scientific" "implies a grounding in the methods and procedures of science." *Daubert*, 509 U.S. at 590.

The Supreme Court has set forth four non-exclusive factors that a court may consider in making its reliability determination: (1) whether the theory or technique can be (and has been) tested, *id.* at 593; (2) whether the theory or technique has been subjected to peer review and publication, *id.*; (3) the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation, *id.* at 594; and (4) whether the theory or technique has general acceptance in the scientific community, *id.* Importantly, the Supreme Court cautioned that the inquiry is "a flexible one." *Id.*; *see also id.* at 593 ("[m]any factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test"); *Dodge*, 328 F.3d at 1222 ("the list is not exclusive").

Finally, the Supreme Court stated that it is not the conclusion reached by the expert, rather the methods used to arrive at the conclusion that are at issue: "The focus [of the inquiry]. . . must be solely on principles and methodologies, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. The Tenth Circuit has stated the same principle this way:

> The plaintiff need not prove that the expert is undisputably correct or that the expert's theory is "generally accepted" in the scientific community. Instead, the plaintiff must show that the method employed by the expert in reaching the conclusion is scientifically sound and that the opinion is based on facts which

sufficiently satisfy Rule 702's reliability requirements.

Mitchell v. Gencorp Inc., 165 F.3d 778, 781 (10th Cir.1999), *see also, Truck Insurance Exchange v. Magnietek, INC*, 360 F.3d 1206, 1210 (10th Cir. 2004).

B. The Biomarker satisfies all of the *Daubert* reliability indicia.

As demonstrated below, the Biomarker is reliable based on all of the *Daubert* criteria.

1. The Biomarker is based on well accepted scientific theory and methodology.

One of the factors suggested by *Daubert* to evaluate the reliability of an expert opinion is consideration of whether the expert's theory has "general acceptance" in the scientific community. While *Daubert* does suggest that "general acceptance" is a factor to be considered by a court, it is careful to note that "general acceptance" is not required under the federal rules. *Daubert,* 509 U.S. at 588-89. The passage of Federal Rule of Evidence 702 liberalized admissions criteria of expert opinions beyond the rigid "general acceptance" test announced in *Frye v. U.S.*, 293 F. 1013 (D.C. Cir. 1923). *Id.* Under the Federal Rules of Evidence, for an expert's testimony to be admissible a litigant, "need not prove that the expert is undisputably [sic] correct or that the experts theory is 'generally accepted' in the scientific community." *Mitchell v. Gencorp, Inc.*, 165 F.3d at 781 (citations omitted). Rather, a litigant must show only that the method used by an expert is scientifically sound and that the expert's opinion is based on sufficient facts to satisfy the reliability requirement of Rule 702. *Id. See also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744-45 (3d Cir. 1994). The Third Circuit in *In re Paoli,* highlighting the "good grounds" requirement of *Daubert* noted that the reliability standard is lower than the merits standard of correctness. *Id.* Further, the Court noted that:

> The grounds for the expert's opinion merely have to be good, they do not have to perfect. The judge might think that there are good grounds for an expert's conclusion even if the judge things that there are better grounds for some

> alternative conclusion, and even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected the scientist would have reached a different result.

In re Paoli, at 35 F.3d 744. In the instant case, it is clear from the evidence provided that Dr. Harwood's conclusions are drawn from scientific methods that are both "generally accepted" and based on "good grounds."

First, it should be noted at the outset that courts have already reviewed the microbial source tracking ("MST") methodology employed by Dr. Harwood to develop the Biomarker - polymerase chain reaction ("PCR") - and have concluded that it is an established, reliable scientific methodology. *See, e.g., United States v. Trala*, 386 F.3d 536, 541 (3d Cir. 2004), *rev'd on other grounds,* 546 U.S. 1086 (2006) (holding that district court did not abuse its discretion in admitting PCR/STR DNA typing as it met the standards for reliability and admissibility set forth in Fed. R. Evid. 702 and *Daubert*); *Stills v. Dorsey*, 7 Fed. Appx. 856, 859 (10th Cir. 2001) (holding that state's admission of PCR evidence was not contrary to federal law); *United States v. Hicks*, 103 F.3d 837, 846-47 (9th Cir. 1996), *cert. denied*, 520 U.S. 1193 (1987) (noting that "novelty" of PCR forensic testing should not prevent district court from exercising its sound discretion in admitting such evidence upon a proper *Daubert* showing); *United States v. Beasley*, 102 F.3d 1440, 1448 (8th Cir. 1996), *cert. denied*, 520 U.S. 1246 (1997) (finding that "the reliability of the PCR method of DNA analysis is sufficiently well established to permit the courts of this circuit to take judicial notice of it in future cases").

In particular, with respect to PCR and its use in the in the science of MST, it has also been accepted as a reliable method of identifying the source of bacteria in the ambient environment. *See, e.g., Quality Assurance / Quality Control Guidance for Laboratories Performing PCR Analysis on Environmental Samples* (EPA 815-B-04-001) (located at

http://www.epa.gov/microbes/qa_qc_pcr10_04.pdf) (recognizing that PCR methods are widely used and are increasingly being applied to analysis of environmental samples); *Microbial Source Tracking Guide* (EPA/600/R-05/064) (located at http://www.epa.gov/nrmrl/pubs/600r05064/600r05064.pdf) (stating that "[g]ene specific PCR methods have been developed for *E. coli* carried by humans, cattle and swine") (citations omitted).

All of the experts in the field of MST in this case agree that the library-independent PCR method of MST has been generally accepted by the relevant scientific community. *See* Exhibit C (Harwood Decl. at para. 3, 20 -25); Exhibit D (Sadowsky Decl. at para. 2); Exhibit F (MacBeth Decl. at para. 7 – 10, and 16); and Exhibit G (Weidhaas Decl. at para. 4, 6, 7 and 12). Dr. Sadowsky, a nationally recognized scholar and expert in MST *see* Exhibit D (Sadowsky Decl. at para. 1) and Exhibit E (Sadowsky CV) states that the methods used by Dr. Harwood for the Biomarker are used by the majority of researchers and companies involved in MST studies and "...they are now recognized by the vast majority of scientists and practitioners as the "gold standard" for MST analyses of water, soil, and sediment". *See* Exhibit D (Sadowsky Decl. at para. 2). Even Dr. Myoda, Defendants' retained expert, acknowledges that the Biomarker methodology is a generally accepted and widely used for MST: "Library independent methods offer many advantages. They have the potential to be considerably cheaper and faster because they do not require the investment in library development. They also have the potential for greater accuracy, since they focus on a specific trait rather than attempting to pattern-match a large number of isolates, some of which may be transient among species." Quote from: Stewart, J.R., R. D. Ellender, J. A. Gooch, S. Jiang, S. P. Myoda, and S. B. Weisberg, *Recommendations for microbial source tracking: lessons from a methods comparison study.* J. Water Health. ,

2003. 1: p. 225-231. Undoubtedly, then, the underlying theory and methodology on which the Biomarker is based is generally accepted by the scientific community and meets this "acceptance" criteria of *Daubert.*

2. The Biomarker's underlying scientific theory and methodology was reliably applied in its development.

Not only is the PCR MST theory and methodology reliable and generally accepted by the scientific community, its theory and methods were reliably applied in development of the Biomarker. *See* Exhibit C (Harwood Decl. at para. 3, and 27 -34), Exhibit F (MacBeth Decl. at para. 3, 4, 7, and 10- 11), and Exhibit G (Weidhaas Decl. at para. 5, 6, 11, 13 and 14). For example, Dr. Harwood explains in her Declaration (which is also detailed in her Report) that development of the Biomarker followed a decade-long history of precedent that has been the model for many other MST assays that identified a target organism. Dr. Harwood developed a PCR assay (or primer) for the unique fragment of bacterial DNA, and tested the primer to determine if it would reliably identify bacteria from poultry waste – and only bacteria from poultry waste. *See* Exhibit C (Harwood Decl. at para. 27-34). Dr. Weidhaas, who was responsible for the laboratory procedures at North Wind (the laboratory that worked with Dr. Harwood), described the step-by-step procedure for the Biomarker development and pointed out that the method was demonstrated to distinguish even one base pair difference in the genetic sequence of the target bacterial DNA sequence (the smallest difference possible). *See* Exhibit G (Weidhaas Decl. at para. 5 and 12)

Defendants' main challenge to the method implementation of the Biomarker appears to be a complaint that the Biomarker is not specific to poultry waste by arguing that not all species of all animals were screened by the Biomarker, and by claiming (through the work of their

retained expert Dr. Myoda) that the PCR assay identifies genetic sequences from waste from non-poultry species. Both arguments are without scientific basis and are based on sound science.

With respect to the argument that the Biomarker must be tested on all species and all individuals within each species, Defendants have conspicuously failed to cite any scientific authority for their position. In contrast, Dr. Hardwood point out that: "***Specificity testing should focus on the non-target fecal sources that are most likely to affect water quality in a given area; it is not possible or necessary to test specificity against every animal species known to exist in the area.***" *See* Exhibit C (Harwood Decl. at para. 25). Dr. Harwood then proceeds to discuss the relevant scientific literature on this issue and points out that EPA has suggested that specificity standards should be established on a case by case basis, but that 80% or greater specificity would have probative value. *See id.* (Harwood Decl. at para. 26). The Biomarker sensitivity evaluation was also was premised on the bacterial mass balance performed by Dr. Teaf for the IRW. *Id.* at para. 13. This analysis provided the basis to focus on livestock (poultry, cattle and swine) which account for 98.6% of the fecal coliform loading to the IRW. *See id.* Therefore, the specificity of the assay was tested against fecal samples from beef and dairy cattle, swine, ducks, geese, and human sewage. *See id.* (Harwood Decl. at para. 30). A total of 116 non-target samples have now been analyzed by qPCR for the Biomarker from Oklahoma, Colorado, Idaho, Florida, Minnesota, Missouri, Ohio and West Virginia. Only eight of these samples (one duck, three goose, and four wastewater treatment plant influent (raw sewage)) samples tested positive for the Biomarker for a specificity of 93%. *See Id.* (Harwood Decl. at para. 38); Exhibit G (Weidhaas Decl. at para.8-9, and 11); and Exhibit F (MacBeth Decl. at para. 11- 12). Thus, the specificity of the Biomarker was tested against those species that have the greatest likelihood of contributing fecal bacteria to the IRW. Testing which was greater than

similar MST studies in published literature and exceeded the EPA Guide Document standard of 80% specificity.

As Dr. Loftis pertinently observed: "This collection is constructed to represent the types of feces that would be encountered in the field. It is highly impractical and unnecessary to include all possible wildlife species in the collection, since the probability of a false positive from most of them is extremely small, as discussed earlier. This is the approach that Dr. Harwood has taken..." See Exhibit H (Loftis Decl. at para.10).

Defendants also argue that the work of their expert Dr. Myoda at his lab (IEH) shows that the Biomarker is not specific to poultry. Unfortunately, Dr. Myoda's opinion and the analysis he relies on should be given little or no weight. His work was fraught with errors. For example, Dr. MacBeth carefully reviewed all of Dr. Myoda's work (and that of IEH) and attended his deposition. She identified the following errors in this work - all of which materially affect Dr. Myoda's opinions on specificity:

a. they did not duplicate the Biomarker protocols appropriately. *See,* Exhibit F (MacBeth Decl. at para. 14, 15, 17, 20, 22, and 24);

b. they did not implement appropriate quality controls and quality assurance. *See,* Exhibit F (MacBeth Decl. at para. 14, 17, 20, 21, 22, and 24) ,

c. they did not interpret their own data correctly. *See,* Exhibit F (MacBeth Decl. at para. 14, 19, and 25); and

d. their lab procedures and layout resulted in contaminated samples. *See,* Exhibit F (MacBeth Decl. at para. 21, 23, and 24).

See also, Exhibit G (Weidhaas Decl. at para.15 - 20) (Dr. Weidhaas specifically faulting Dr. Myoda's work and that of IEH and quoting EPA Guidance demonstrating the mistakes made).

Indeed, Dr, Myoda in his deposition acknowledged the importance following protocols and QA/QC procedures. *See* Exhibit I (Myoda depo. at 29:18-31:14).

In sum, the Biomarker was carefully developed according to relevant methods and procedures to identify poultry waste DNA in the IRW. Not only is the underlying theory and methodology for the Biomarker well accepted, its specific application was reliably performed by Dr. Harwood and her colleagues at North Wind Labs as required by Rule 702 ("... the witness has applied the principles and methods reliably to the facts of the case").

3. The Biomarker is capable of being tested and has been subject to testing.

Often important to the reliability analysis is the question as to whether the method or technique can be tested. As noted by the *Daubert* Court, scientific method today is based on testing of hypothesis and empirical testing. *Daubert* 509 U.S. at 593. The Biomarker is not only capable of being tested; it has already been tested by two researchers: Defendants' expert Dr. Myoda and Dr. Mike Sadowsky, Distinguished McKnight University Professor in the Department of Soil, Water and Climate at the University of Minnesota.

The Defendants do not contend that the Biomarker was not capable of testing. Thus, it plainly satisfies one part of the *Daubert* analysis - whether the theory or technique can be (and has been) tested. *Daubert* 509 U.S. at 593. As discussed above, Dr. Myoda and his lab tested the methods of the Biomarker. Unfortunately, his test results, for the most part, cannot be relied on due to the errors described above. Fortunately, however, Dr. Sadowsky performed a blind test (discussed in more detail below) and validated the Biomarker methodology. *See* Exhibit D (Sadowsky Decl. at para. 3-12). Thus, the Biomarker satisfies this element of *Daubert* reliability.

4. **The Biomarker has been peer reviewed.**

Another aspect or test of reliability listed by the Supreme Court in *Daubert* is peer review and publication of the method. The Supreme Court made clear, however, two important aspects of this test. First, publication is but one type of peer review and second, publication is not the *sin qua non* of admissibility:

> Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded but innovative theories will not have been published. Some propositions, moreover, are too particular, too new, or of too limited interest to be published. But submission to the scrutiny of the scientific community is a component of "good science," in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Daubert, 509 U.S. at 593-594 (1993) (citations omitted). Thus, the Court acknowledged that there are other forms of peer review than publication in a scientific journal. It also acknowledged that either acceptance or rejection of publication should not be the "litmus test" or *sine qua non* of reliability. Indeed, it would seem that the most reliable method of peer review would be a blind test - either confirming the method or not – by a respected scientist accomplished in the scientific field in question. This is exactly the test that the Biomarker was subjected to.

Dr. Sadowsky, Distinguished McKnight University Professor in the Department of Soil, Water and Climate, and The BioTechnology Institute at University of Minnesota, St. Paul, and also the current co-director of the Microbial and Plant Genomics Institute, the Director of the Microbial Ecology Minors Graduate Program, and co-Director of Graduate Studies of the Soil Science Graduate Program at this University, agreed to test and peer review the Biomarker by employing a blind study – that is, he tested the samples without knowledge of their origin. *See*

Exhibit C (Harwood Decl. at para. 3 and 40), Exhibit D (Sadowsky Decl. at para. 3-4), Exhibit F (MacBeth Decl. at para. 15), and Exhibit G (Weidhaas Decl. at para. 15).

Dr. Sadowsky, who is described by Defendants' expert Dr. Myoda as having a good reputation and being a careful and meticulous researcher s*ee,* Exhibit I, (Myoda Depo at pp. 210:23-211:7), completely validated and replicated the Biomarker through the blind test. *See* Exhibit C (Harwood Decl. at para. 3 and 40); Exhibit D (Sadowsky Decl. at para. 4-12); Exhibit F (MacBeth Decl. at para. 15); and Exhibit G (Weidhaas Decl. at para. 15). As a result of that work Dr. Sadowsky has opinined: "Based on these analysis, I conclude that [the Biomarker] primers are a reliable tool to identify contaminated poultry litter and its presence in soil and water samples." *See* Exhibit D (Sadowsky Decl. at para. 12). Additionally, Dr, Sadowsky states that the validation studies he performed are being used for a Masters of Science thesis dissertation of a student in the Microbial Engineering Graduate Program at the University of Minnesota and that these results have been presented in the form of a poster presentation, at the North Central Branch Meeting of the American Society for Microbiology. *See Id.* (Sadowsky Decl. at para. 13).

This work by Dr. Sadowsky not only satisfies the peer review test, it also shows that the Biomarker has been tested and it is reliable. Arguably, this method of peer review is much preferred to publication. As pointed out by both Drs. Sadowsky and Loftis (both of whom have sat on editorial boards for scientific journals and reviewed many papers themselves that were submitted for publication, the anonymity of the reviewers for publication in journals does not allow a court to determine the credentials and potential bias of the reviewer. *See* Exhibit D (Sadowsky Decl. at para. 14) and Exhibit H (Loftis Decl. at para.21). Here, Dr. Sadowsky is

disclosed and his credentials are exemplary in the area of MST and library independent PCR – the very same methods used with the Biomarker.

The Defendants attempt to make great moment of the rejection of the paper submitted by Harwood, *et al* to the Journal of Applied Microbiology ("JAM"). Again, given the anonymity of the reviewers we cannot tell whether they had qualifications to judge the work represented by the paper. Further, it appeared that the primary basis for rejection had little to do with scientific reliability, and more to do with the applicability of the Biomarker outside of the IRW. *See* Defendants' Motion, *Exhibit* 7, p. 1. This scope concern has been resolved based on additional research by these investigators, and, in any event, should not be basis to deem the Biomarker as unreliable, rather it is a question of relevance and the comment of the reviewers indicates that the Biomarker clearly it *is* relevant to this case located in the IRW. *See,* Exhibit C (Harwood Decl. at para. 3 and 41-42). Finally, the concerns raised by the reviewers from JAM have been addressed by additional research. *See Id.* (Harwood Decl. at para. 3 and 41-42). [1]

5. The Biomarker has a known or potential rate of error.

The final reliability consideration expressed in *Daubert* concerns whether the method has a known or potential rate of error. Based on the testing performed by both Dr. Harwood with the North Wind Lab as well as the testing by Dr. Sadowsky at the University of Minnesota lab, there is an established rate of error for both the sensitivity (false negative) and specificity (false positive) for the Biomarker. *See* Exhibit C (Harwood Decl. at para. 25 and 43); Exhibit G (Weidhaas Decl. at para. 8) ("The biomarker PCR … has a known rate of error based on that specificity…"); and Exhibit H,(Loftis Decl. at para. 10-13). As Dr. Harwood observed: "It is worth noting that the probability of a false-negative (failure to detect the target when

[1] It should also be noted that the Defendants' counsel likely influenced the publication process by submitting comments that were prepared by their retained expert Dr. Myoda. These comments suffered from the same errors in Dr. Myoda's expert report.

contamination from poultry is present) is greater than the probability of a false-positive (detection of the target when contamination from poultry is absent)." *See,* Exhibit C (Harwood Decl. at para. 43). Thus, if there is an error in application it will most likely inure to Defendants' benefit.

6. Defendants' arguments based on "standard" fate and transport and "statistics" are not support by the record.

a. The State has performed well recognized fate and transport analysis applicable to this case.

Defendants seem to believe that if they say something enough, it will somehow become true. Despite Defendants' repeated arguments to the contrary, however, the State did conduct a thorough fate and transport analysis – one that is both traditional and applicable to the chemicals and disposal practices at issue in this case. That analysis demonstrates the presence of contamination from poultry waste at each environmental step of the fate of their waste following its generation - from the poultry houses, to the edge of fields where it is applied, leaching into groundwater and running off into streams, rivers, and finally, as it must because or gradients and gravity, traveling into the waters and sediments of Lake Tenkiller. This analysis supports and is consistent with the Biomarker and the opinions offered by Dr. Harwood concerning the risks associated with the land application of over 350,000 tons of poultry waste each year in the IRW.

As a brief summary, and not as a complete review, the State can refer to Drs. Fisher, Engel, Teaf and Olsen expert reports and the detailed evidence cited therein about the fate and transport work done in this case. First, their work reveals that land applied poultry waste in the IRW is a significant and substantial source of phosphorus and bacteria. This analysis is based on the amount of waste generated, how it is managed (a significant portion of the waste generated is land applied in the IRW) and the time period over which such waste was generated and disposed

of in the IRW. *See Hatco Corp. v. W.R. Grace & Co.-Conn.*, 836 F. Supp. 1049, 1059 (D.N.J. 1993) (discussing traditional causation analysis in environmental case considers amount, time and methods of waste management). Furthermore, Dr. Fisher studied the geology of the IRW to determine how poultry waste is transported in the environment based on the karst, fractured geology and the studies and tests demonstrating runoff and leaching of poultry waste constituents from land applied fields. In addition, the States experts conducted extensive sampling in the IRW. Relying on that sampling, the existing and ongoing sampling by the USGS and other entities as well as previously published governmental reports and the work done by University investigators, the State's experts, including Drs. Fisher, Engel and Olsen, studied the constituents of poultry waste and followed the movement of those constituents, and their concentration gradients, each step along the pathway — beginning with the waste itself, then the fields, the edge of fields, the surface water, sediments, springs, ground water of the IRW, and finally Lake Tenkiller. Dr. Fisher also performed a paleolimnological investigation of the sediments of Lake Tenkiller and determined that the increased levels of phosphorus in the sediments showed increasing phosphorous correlated with the increased levels of other constituents commonly found in poultry waste, which further buttresses his opinion regarding the source of contamination in the IRW. Dr. Engel also implemented several a watershed models demonstrating that poultry waste significantly contaminates the waters of the IRW.

Defendants claim in their Motion that there are cases that describe a "traditional fate and transport" analysis. Thereby implying that such an analysis is necessary. However, the cases cited by Defendants neither require nor identify such a "traditional" analysis. Further, each of the cases cited by Defendants fails to articulate what such analysis is or whether such an analysis is required. Furthermore, Defendants' authority is readily distinguishable from the case

at hand. For example, each of the cases cited by Defendants center around synthetic pollutants which behave differently in the environment than phosphorus and bacteria. *See Hatco Corp. v. W.R. Grace & Co.-Conn.*, 836 F. Supp. 1049 (D.N.J. 1993) (base neutrals (BNs), polychlorinated biphenyls (PCBs) and volatile organic compounds (VOCs)); *Kalamazoo River Study Group v. Eaton Corp.*, 258 F. Supp. 2d 736 (W.D. Mich. 2003) (PCBs); *Allgood v. GM Corp.*, 2006 WL 2669337 (S.D. Ind. Sept. 18, 2006) (PCBs); *City of Wichita v. Trustees of APCO Oil Corp. Liquidating Trust*, 306 F. Supp. 2d 1040 (D. Kan. 2003) (VOCs).

Finally, there really is no "traditional" fate and transport analysis like the Defendants would like to propose for the microbial field. However, Dr. Harwood points out that the expected pathway of bacteria was followed from land applied litter, the applied fields and the edge of such fields during run off events and the expected bacterial impact from poultry litter was observed. *See,* Exhibit C (Harwood Decl. at para. 17). This, along with other evidence collected by the State, support the Biomarker and Dr. Harwood's opinions concerning risk. *See,* Exhibit C (Harwood Decl. at para. 3-19)

b. Defendants' statistical analysis is not based on the record or environmental science.

Defendants argue that Dr. Harwood failed to use statistically significant sample numbers for the Biomarker analysis. Peer-reviewed, published articles employing MST, however, have used the same or fewer samples used by Dr. Harwood in the Biomarker development. *See* Exhibit C (Harwood Decl. at para. 43). Dr. Loftis, and expert in nonpoint source pollution and environmental statistics makes several important observations about Defendants' statistical concerns and the opinions of their retained expert Dr. Cowan. *See* Exhibit H (Loftis Decl. at para. 6-13). Dr. Loftis points out the fallacies of Dr. Cowan's analysis and concludes that his interpretations and opinions are "based on assumption" *see id.* (Loftis Decl. at 9), that his

interpretation is "at best, extremely misleading, *see id.* (Loftis Decl. at 11), and "ignores the fact[s]" *see id.* (Loftis Decl..at 12). Thus, Defendants' argument that Dr. Harwood's methodology is in doubt because she did not test every animal in the watershed is simply lacks any foundation. As noted in her Declaration, Dr. Harwood tested animals with the greatest potential for contributions to watershed: humans, cattle, swine, ducks, and geese. Further analysis would have been unfruitful based on the amount of feces contributed to the watershed by other species. Dr. Harwood cannot be faulted for failure to test muskrat and terrapin feces as Defendants propose. *See* Exhibit C (Harwood Decl. at para. 13 and 43)

Defendants also criticize Dr. Harwood's work arguing that there is no statistical correlation between the poultry biomarker and fecal indicator bacteria found in the watershed. This assertion is just plain wrong. First, Dr. Harwood's Report discusses the correlations of the poultry biomarker to enterrococus. *See* Exhibit A (Report at Figure 4) & Exhibit C (Harwood Decl. at para. 35). The Defendants' claim is based on Dr. Myoda's work product. However, as pointed out by Dr. Loftis, Dr. Myoda failed to log transform his data when he did the correlation evaluation. *See* Exhibit H (Loftis Decl. at para. 14-20). This failure, plus the other mistakes noted by Dr. Loftis is an attempt by Dr. Myoda to suggest that "there was no correlation when in fact there was." *See id.* (Loftis Decl. at 15).

C. Dr. Harwood's opinions on the risk of land applied poultry waste are well founded and support by reliable tests.

Dr. Harwood reached the conclusion that the spreading of fecal-contaminated poultry waste on fields in the IRW represented a threat to human health prior to the development and use of the Biomarker. Moreover, that opinion was not based solely, or even substantially, on the Biomarker. Rather, her opinion was based on the weight of evidence represented by data from published literature, land use, the amount of litter applied to fields, the pathogens that are known

to be shed in poultry feces, environmental sampling and analysis, and the hydrology and geology of the IRW. *See* Exhibit C (Harwood Decl. at para. 3). Contrary to Defendants' claim that the Biomarker was developed to support her opinion on risk, according to Dr. Harwood, "[t]he poultry litter biomarker is one tool among many used to build the weight of evidence that land application of poultry litter represents a substantial danger to human health. *See id.* (Harwood Decl. at para. 3) Indeed, in her Report and again in her Declaration, Dr. Harwood details the substantial evidence that supports her opinion concerning the public health threat associated with the current practice of land application of poultry waste. *Se,* Exhibit C (Harwood Decl. at para. 3-19, & 45).

Thus, this opinion was arrived at by Dr. Harwood *before* the memo written by the State's counsel that Defendants like to point to as evidence that the Biomarker was a creation of counsel. *See* Defendants' Motion, Exhibit 12. Therefore, the claim by Defendants' that the Biomarker opinion was prompted by counsel and litigation generated is a misleading interpretation of new facts by Defendants.

Finally, Defendants' argument relating to sample hold times is another red hearing. As Dr. Harwood states following a review of the relevant scientific literature: "Thus, the effect of extended holding time is that bacterial concentrations will be *lower* than if the analysis was done immediately. Most studies, however, have found that no significant differences result when samples are held 24-48 hours at 8 - 10° C (refrigerated or on ice)." *See* Exhibit C (Harwood Decl. at para. 12). Again, Dr. Harwood's scientific analysis and study of the IRW is shown to be scientifically reliable and valid.

III. Conclusion

All of the *Daubert* factors weigh in support of reliability of the Biomarker. Indeed, much work has occurred since the preliminary injunction hearing. Additional research and analysis has confirmed the reliability of the Biomarker. It is clear that the Biomarker is supported by reliable scientific methods and application. Moreover, Dr. Harwood's opinion on the risk of land applying poultry waste predated Biomarker development and also rests on a sound scientific foundation and facts. Thus, Dr. Harwood's opinions are not litigation driven and were not developed by counsel. Accordingly, Defendants' Motion should be denied in all respects.

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